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PHARMACEUTICALS AND MEDICAL DEVICES

¶1. Taiwan has identified both the medical device and pharmaceutical sectors as priorities for development, resulting in Taiwan agencies sometimes appearing to favor the interests of local companies over foreign firms. In addition, Taiwan bans imports from China of about 30 medical products. Due to global manufacturing plans, however, many U.S.-designed medical devices are produced in China, and the foreign medical device industry has suggested that Taiwan lift import bans for these products. In response, the Ministry of Economic Affairs (MOEA) recently announced that it would conditionally allow the import of blood glucose meters made in China.

¶2. Improvements have occurred in the registration and approval process for less risky medical devices in recent years. However, registration and approval procedures for higher risk medical device imports are complex and time consuming, and continue to be the subject of longstanding complaints by U.S. firms. The registration process requires extensive documentation and sometimes arbitrary demands for additional information and redundant testing.

¶3. DOH officials are therefore continuing to work with industry to improve the medical device registration process, primarily concerning identical products made in different quality system documentation manufacturing sites, or with outer packaging changes. In order to make product registration more efficient, the DOH recently adopted more flexible product registration procedures for in-vitro diagnostic medical devices that allow importing companies to follow U.S. or EU procedures, rather than demand extensive documentation and redundant testing for products made in Europe by U.S. companies. Regulations are vague on when local clinical trials are required for the review process or whether industry is allowed to provide additional input in response to questions posed by DOH officials reviewing the clinical trial submissions.

¶4. A continuing concern in the pharmaceutical sector in Taiwan involves pharmaceutical pricing and management. Through the TIFA process, the United States has been encouraging Taiwan to adopt a system of actual transaction pricing (ATP) in order to address the significant gap between the amount that the Bureau of National Health Insurance (BNHI) reimburses for a pharmaceutical product and the price actually paid to the provider of that product. This gap distorts pharmaceutical trade and prescription patterns in Taiwan. These distortions are worsened by hospital doctors' ability to both prescribe and dispense pharmaceuticals. Separating these functions would help to resolve the long term pricing problem.

¶5. In addition, Taiwan's lengthy pharmaceutical registration process imposes unnecessary costs and slows market entry for new drugs that have already received regulatory approval in advanced economies. For example, the Taiwan Department of Health (DOH) Bureau of Pharmaceutical Affairs (BOPA) requires a company that wants register a drug for sale in Taiwan to provide Certificates of Pharmaceutical Product (CPP) certifying the drug for sale in two separate markets outside Taiwan. BOPA, however, is considering new registration

procedures that would reduce the current requirement to one CPP, which would help speed introduction of new pharmaceuticals--especially U.S.-made drugs--into the Taiwan market.

¶6. The reimbursement price gap noted above for pharmaceuticals is also an issue for medical devices offered in the Taiwan market. In addition, BNHI pricing criteria currently specifies a single purchase price for all medical devices that treat the same indication. This policy effectively subsidizes lower quality, often domestically-made devices while forcing producers of high-priced, high-value devices to be reimbursed at an insufficient level. Unless the policy is modified, this may lead to significant market distortion in favor of lower quality products over time.

¶7. Through the TIFA process, the United States is encouraging Taiwan's Ministry of Justice and DOH to work together to take action to resolve pharmaceutical pricing and reimbursement problems. The DOH has agreed to set up working groups to study options to bring more transparency and fairness to drug pricing, including requiring standard contracts for all drug purchases, implementing ATP, and separating dispensing and prescription. In September 2007, Taiwan's Executive Yuan approved a proposed amendment to the National Health Insurance (NHI) Law that would increase pricing transparency by requiring all hospitals to use a common standard contract for pharmaceutical purchases; the amendment is pending approval by the Legislative Yuan.

GOVERNMENT PROCUREMENT

¶8. Taiwan committed to accede to the GPA as soon as possible after it became a WTO Member, but it has not yet acceded due to differences with GPA Parties regarding nomenclature issues. To prepare for accession, Taiwan implemented a new government procurement law in mid-1999, an important first step toward establishing a transparent and predictable environment for Taiwan's multi-billion dollar public procurement market. In August 2001, Taiwan and the United States signed a Memorandum of Understanding on Government Procurement (MOU). The MOU calls for Taiwan to implement certain procedural commitments immediately, with others to be implemented upon accession to the GPA. The United States continues to work with the Taiwan authorities to resolve nomenclature issues and permit Taiwan accession.

¶9. Many Taiwan procurement contract clauses specifically exclude foreign tenders. In addition, Public Construction Commission (PCC)-determined terms and conditions for model public procurement projects impose large indirect and unforeseeable liabilities on contractors and thereby prevent U.S. firms from bidding on projects.

EXPORT SUBSIDIES

¶10. Taiwan provides incentives to industrial firms in export processing zones and to firms in designated "emerging industries." Taiwan has notified the WTO of these programs and, as part of its WTO accession, committed to amend or abolish any subsidy programs inconsistent with WTO rules. When it became a WTO Member, Taiwan amended relevant laws, such as the Statute for Establishment and Management of Economic Processing Zones and the Statute for Establishment of Scientific Industrial Parks. The United States continues to monitor Taiwan's compliance with the commitments it undertook as part of its WTO accession, including those obligations associated with the Agreement on Subsidies and Countervailing Measures.

INTELLECTUAL PROPERTY RIGHTS (IPR) PROTECTION

¶11. IPR protection continues to be an important issue in the United States-Taiwan trade relationship. The United States recognizes Taiwan's continuing efforts to improve enforcement of IPR in 2008, but continues to be concerned with a number of issues, including the availability of counterfeit pharmaceuticals in Taiwan, Internet infringement, illegal textbook copying on and around university

campuses, and inadequate protection for the packaging, configuration, and outward appearance of products (trade dress). The U.S. International Intellectual Property Alliance estimates that losses due to IPR copyright piracy in Taiwan cost U.S. industry $327.8 million in 2007. Transshipment of counterfeit products from China is also a problem. Counterfeit goods from Taiwan seized by U.S. Customs dropped from $26.5 million in 2002 to $3.4 million in 2007 and to $1.3 million in the first half of 2008.

¶12. Trademark counterfeiting, particularly of clothing and luxury goods, is still a concern. Much of the counterfeit product is reportedly smuggled from China. Rights holders state that Taiwan is both a transshipment point and a market for this counterfeit material. Taiwan Customs and IP police make regular seizures of counterfeit apparel and handbags, but rights holders complain that investigation and prosecution remain hampered due to inadequate resources and personnel and that light sentences issued for convictions do not deter trademark counterfeiters.

¶13. Internet piracy and illegal peer-to-peer (P2P) downloading remain serious concerns for IP enforcement in Taiwan, and the sale of counterfeit goods over the Internet - resulting in part from increased raids on traditional sales venues - is also a concern. Taiwan has made efforts to combat such Internet-related IPR violations, including strengthening cooperation with foreign enforcement agencies and passing an amendment to the Copyright Law in June 2007 that subjects illegal file sharing to a maximum jail term of two years. Also, the authorities are amending the Taiwan Copyright Law to require Internet service providers (ISP) to undertake more effective notice-and-takedown actions against online infringement. To improve Taiwan's ability to protect IPR on college campuses, Taiwan continued its Campus IPR Action Plan to strengthen management of academic computer networks and illegal textbook copying by students.

¶14. The United States remains concerned about counterfeit pharmaceutical products in the Taiwan market. The recent revision of the Pharmacist Law increased penalties for pharmaceutical counterfeiting, and the Ministry of Justice, the Taiwan Coast Guard, and Taiwan Customs have had some success in intercepting imports of counterfeit pharmaceuticals. Nevertheless, counterfeit products continue to be a threat to public health in Taiwan, and may undermine confidence in legitimate products.

¶15. U.S. rights holders report that court procedures and delays can constitute impediments to effective IPR enforcement and that penalties for intellectual property infringement are inadequate to deter violators. In addition, Taiwan's judiciary continues to experience difficulties handling technically challenging IPR infringement cases. To improve this situation, Taiwan established a specialized IP court in July 2008, and the United States continues to assist Taiwan to remedy weaknesses in the judicial system by providing training and holding seminars on different criminal enforcement issues.